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STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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PHARMACY & THERAPEUTICS COMMITTEE

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV

Committee Approved
Meeting Minutes
December 11, 2008

Committee Members Present:
Linda Flynn, R.Ph.
David Chan, R.Ph.
Constance Kalinowski, MD
Michael Karagiozis, DO
John Lee, MD
Chad Luebke, Pharm.D.
R.D. Prabhu, MD
Chris Shea, Pharm.D.

Absent:
Justin Holt, Pharm.D.
Rudy Manthei, DO

Others Present:
Mary Griffith-DHCFP, Darrell Faircloth, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Mike Steelman-Pfizer, Gary Alling-NNI, Lori Howarth-Bayer, John Robinson-Boehringer Ingelheim, Dan Bay-Abbott, Isam Herndon-GSK, Steve Brudzawski-Pfizer, Jane Stephen-Allergan, Carlos Talasciano-Hawthorn, Shawn Prince-Elan, Sandy Sierawski-Pfizer, Arezo Fathie, MD, Kirk Huffaker-SP, Cijaye Mullen-Eli Lilly, Tremell Turner-Eli Lilly, Rob Chiascione, MD, Sarah Day-VCG & Associates, Emil Milas-GSK, Lisa Wilson-Ortho McNeil Janssen, Laura Litzenberger-Ortho McNeil Janssen, Robert Spivock-Gilead, Aaron Huwe-Gilead, Penny Atwood-Boehringer Ingelheim, Kara Thorsfeldt-Cephalon, R. Lynn Horne, MD-UNSOM, Lee Boyle-Shire, Steve Farmer-Amgen, Eric Farbman-UNSOM, Guli Tefferi-Eisai.

I. Call to Order and Roll Call

Vice-Chair, Linda Flynn, called the meeting to order at 1:01 p.m.

Mary Griffith announced that a new member has been appointed to the Committee, Constance Kalinowski, MD. Dr. Kalinowski is a general psychiatrist currently practicing at Mohave Adult, Child and Family Services in Las Vegas, and is also a member of the faculty of the University Of Nevada School Of Medicine. She graduated from Georgetown University and completed her residency at the University of Wisconsin. She specializes in treating adults with intellectual disabilities. Her background has been in mental health and psychosocial rehabilitation.

II. Review and Approval of September 25, 2008 Meeting Minutes

A quorum of the Committee members was not present for the motion. Review and approval of the minutes will be postponed until the March meeting.

Ms. Flynn stated that under item III.B. Antiparkinson's Agents, only the dopamine agonists will be considered and under item IV.A, only the triglyceride lowering agents will be considered.

Ms. Flynn announced that at the request of Dr. Karagiozis, that Agenda Item IV.A., Triglyceride Lowering Agents, will be taken out of order and addressed as the next item of business following roll call and the review of minutes.

III. New Drug Class Reviews

A. Alzheimer's Agents

Public Comment

Dr. Robert Lynn Horne stated that he is speaking today as professor of psychiatry of the University Of Nevada School Of Medicine. He disclosed that he has been a speaker for all and consultant for some manufacturers of acetylcholinesterase inhibitors. Per his agreement with the Attorney General's Office, funds received as honorariums or for consultant fees during his time on the P&T Committee to the present, have gone to one of four charities. He is not being paid a fee today but representing his views. He stated that all of the medications in this class are therapeutic alternatives and requested that whatever medication the patient is currently on, be grandfathered in forever. His concern is that if a patient has to change from the medication they are currently taking to another, there will be a period of time that the patient will deteriorate greatly and be down to where they would have been if they had never taken it. He cited studies where patients on Aricept® showed improvement over baseline, but when taken off the drug, declined six to ten points.

Sandy Sierawski, Pfizer, spoke in support of Aricept®. Aricept® is the only monotherapy indicated for all stages of Alzheimer's disease (AD). It is the number one prescribed AD therapy across the nation and is demonstrated in Nevada Medicaid's data. CMS prescription data for the first two quarters of 2008 indicated that Aricept® had 65% of the prescriptions; Namenda® had 32%; Exelon® and Razadyne® had 2% each. Aricept's® efficacy and safety have been demonstrated in eighteen controlled studies. It causes few adverse events and has a low discontinuation rate. Advantages include once-daily dosing; can be taken with or without food; does not require titration to achieve an effective dose. Guidelines from the Alzheimer's Disease Management Council Consensus Panel and Scientific Roundtable recommend that those who have been successfully titrated and tolerate a therapeutically effective dose should be maintained on that therapy. She cited a study which the results suggested that patients on Aricept® who had treatment interrupted for six weeks and then were restarted, never regained the same cognition that was achieved before discontinuation of therapy. She recommended continued access to Aricept® to assure quality of care for patients.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that there are four acetylcholinesterase inhibitors approved for treatment for mild to moderate Alzheimer's: Aricept®, Razadyne®, Exelon® and Exelon® Patch and Cognex®. Aricept® is also approved for moderate to severe AD. The fifth agent in this class, Namenda®, is approved only for moderate to severe AD. It has a different mechanism of action. Namenda® is not a cholinesterase inhibitor; it's an NMDA receptor antagonist. There is data that state that Namenda® can be used with the cholinesterase inhibitors and it has been beneficial in moderate to severe AD when used in combination. All of these agents have been shown to give statistical improvement. Interpretation of the significance can be challenging and the evidence on the quality of life is mixed. There is no convincing evidence stating that one product is better than another. Unfortunately, a high percentage of patients do not respond. In patients that do respond, the symptomatic relief is moderate and the duration of effect may be limited. There is no evidence that these drugs alter the course of the disease and it is unknown if there is any impact on nursing home placement or mortality. Despite the small treatment effect, the cholinesterase inhibitors are recommended for first-line treatment by the American Academy of Neurology in patients with mild to moderate AD primarily due to the lack of effective alternatives. In terms of adverse events, the effectiveness of the cholinesterase inhibitors is limited by the maximum tolerated dose. Patients are titrated

slowly to avoid gastrointestinal effects (GI). Exelon® does not have an impact on the CYP450-mediated drug interactions which is an advantage in some patients. Namenda® does not have the GI effects which can be seen with cholinesterase inhibitors. Cognex® is rarely used because of hepatotoxicity. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Constance Kalinowski motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Michael Karagiozis
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that Aricept® tablets, Exelon® capsules, patch and solution, and Namenda® be included on the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

MOTION: Constance Kalinowski motioned to accept First Health's recommendation to include Aricept® tablets, Exelon® capsules, patch and solution, and Namenda® on the PDL.
SECOND: Michael Karagiozis
VOTES: Unanimous
MOTION CARRIED

B. Antiparkinson's Agents -Non-Ergot Dopamine Receptor Agonists

Public Comment

John Robinson, Boehringer Ingelheim, spoke in support of Mirapex®. Mirapex®, a dopamine agonist, has been shown in clinical trials to improve motor function and to help delay the onset of levodopa induced motor complications. Mirapex® is rapidly absorbed, approximately two hours, and has a high bioavailability of greater than 90%. It can be taken with or without food. No dosage adjustment is necessary in patients with hepatic insufficiency as urinary excretion is the major route of pramipexole elimination with 90% of the dose recovered in the urine. Dose adjustment is required in patients with renal failure receiving hemodialysis. An effective dose ranges from 1.5mg to 4.5mg per day administered on a TID basis with or without levodopa. He cited the CALM-PD Trial which compared Mirapex® with levodopa. Mirapex® as monotherapy was shown to improve motor function and activities of daily living. Mirapex® as an adjunctive therapy in Parkinson's Disease (PD) was shown to help increase duration and quality of on time and to reduce the severity of off time, improve tremors and reduce levodopa dosing. Hallucinations and orthostatic hypotension may occur with Mirapex®. The most commonly reported adverse events in early and late disease clinical trials were dizziness, dyskinesia, extra pyramidal syndrome, hallucinations, headache, insomnia, somnolence and nausea. Mirapex® is well-tolerated in both early and late PD; there are no predicted 450 interactions.

Eric Farbman, MD, neurologist with the University Of Nevada School Of Medicine disclosed that he has spoken for many companies but he is not being compensated for his testimony today. He stated that at one point there have been up to five dopamine agonists approved in the United States. Currently, there are only two available, Requip® XL and Mirapex®. Both products are extremely effective and should be available. Most PD

patients are elderly and do not have Medicaid. Those that have Medicaid are younger with more severe disease. Dyskinesia tends to occur in younger individuals that are on levodopa for a long time; the extreme example would be Michael J. Fox. Requip® XL is very useful because it's once daily dosing and provides continuous dopamine stimulation which is closer physiologically. There are good studies with Mirapex® for using it with depression and Parkinson's as well as with the motor symptoms. He recommended that both Mirapex® and Requip® XL be available.

Dr. Shea asked if Dr. Farbman ever uses an immediate release agonist with an extended release or some type of combination therapy to mediate those on and off periods. Dr. Farbman replied that he would not put a patient on two agonists. The problem with agonists when compared to Sinemet® is that the patient needs to be titrated up. If the patient has not been on another drug before, immediate release Sinemet® provides symptom relief within twenty minutes. Then there are the problems with dyskinesia and other motor side effects so there would be no other drugs added with Sinemet®.

Marilyn (last name inaudible), Glaxo Smith Kline, spoke in support of Requip® XL. She stated that in reference to the question regarding the combination of immediate release and extended release in the case of Parkinson's disease patients, one of the key areas for therapy is to have a drug that is going to mimic the release of dopamine within the body that didn't have PD. People without PD have a steady release of dopamine throughout the day. The problem with the immediate release formulations are the peaks and troughs due to the short half-life of the dopamine agonists. The extended release formulation of Requip® mimics the release of dopamine in the body that didn't have PD. Requip® XL tablet is available in four strengths, 2mg, 4mg, 8mg, 12mg. It has been studied in advanced stage patients as adjunct to levodopa and studied in onset patients. A patient on three times per day Requip® can easily be converted to the extended release by matching the dose and starting the extended release once-a-day dosing the next day.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that the focus of this drug class today is on the non-ergot dopamine agonists. The other agents in this dopamine agonist category are available without PDL restriction. The agents being considered today are pramipexole (Mirapex®) and ropinirole (Requip® and Requip® XL). The immediate release formulation of Requip® is available generically as ropinirole. Rotigotine (Neupro®) has been removed from the market due to problems with the transdermal system. These agents are often used as part of early therapy for Parkinson's Disease. They can be used as effective adjuncts to levodopa and are often used effectively as initial therapy to delay the need for levodopa therapy and its side effects. Although not considered first-line, Mirapex® and ropinirole immediate release are also indicated for Restless Leg Syndrome (RLS). Adverse events for these agents are similar. All are associated with agonist-specific side effects, orthostatic hypotension, confusion, sedation and can lead to hallucinations and psychosis due to the cholinergic nature of the drugs. It is the recommendation of DHCFP and First Health that the non-ergot dopamine agonists be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: **Michael Karagiozis motioned that the non-ergot dopamine agonists be considered therapeutic alternatives.**
SECOND: **Chris Shea**
VOTES: **Unanimous**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health to add Mirapex® and generic ropinirole to the PDL.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

Chad Luebke asked why the extended release is not being recommended. Dr. Monaghan replied that once there is a therapeutic equivalency statement by the Committee, DHCFP and First Health can take cost into account when doing their analysis and making their recommendation. Cost is not discussed with the Committee.

Dr. Karagiozis referred to opinions expressed in public testimony that multiple doses during the day are not as good for patient management as maintaining physiologic levels of dopamine throughout the day. Dr. Monaghan responded that there appears to be an advantage, but in the first quarter of 2008, there was one claim for the extended release. Ropinirole generic immediate release is being dispensed 60% of the time.

Dr. Lee asked if First Health's position is to see more outcomes data that the extended release is superior in terms of outcomes. Dr. Monaghan agreed and added that there will be another opportunity to review this class at the annual review in June 2009.

Dr. Karagiozis stated that if this Committee is not to discuss cost, the fact that cost is not discussed should not come up. This Committee should restrict the discussion to drug to patient.

David Chan asked if the extended release will be available to the patient through the PA process and Dr. Monaghan replied yes.

Dr. Luebke felt that in this Medicaid population, there is benefit from going from TID dosing to QD dosing for the average patient in this population. Dr. Monaghan stated he did not disagree with that logic.

MOTION: **Chad Luebke motioned to include Mirapex®, ropinirole and Requip® XL on the PDL.**
SECOND: **Michael Karagiozis**
AYES: **Luebke, Prabhu, Chan, Karagiozis, Kalinowski, Flynn, Shea**
NAYES: **Lee**
MOTION CARRIED

C. Platelet Aggregation Inhibitors

Public Comment

John Robinson, Boehringer Ingelheim, spoke in support of Aggrenox®. Aggrenox®, one capsule (aspirin 25mg/dipyridamole 200mg), administered BID is indicated for prevention of recurrent stroke in patients who have had a previous stroke or transient ischemic attack. Each dipyridamole pellet has an extended release coating in a core of an acidic environment which enhances absorption. In individuals with gastric acid, the extended release dipyridamole in Aggrenox® provides 50% higher bioavailability than an immediate release dipyridamole. The prescribing information contains a cautionary statement that is mandated by the FDA that states Aggrenox® is not interchangeable with individual components of aspirin and Persantine® tablets. It has been shown to be twice as effective for stroke prevention as aspirin administered alone. He referred to the ESPS-2 trial in which Aggrenox® showed a 22% relative risk reduction for stroke compared with aspirin.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that the drugs being considered in this category are Aggrenox®, Plavix®, dipyridamole, ticlopidine, and suggested that if the PDL is something that influences therapy, consideration be given to adding aspirin to the list. The platelet

aggregation inhibitors are used to prevent and treat a variety of thrombotic events including MI, stroke, TIA and peripheral arterial disease. The published guidelines for the use of these agents are extensive. In terms of adverse events, ticlopidine distinguishes itself due to the serious hematologic effects and the product literature contains a black box warning regarding this. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Lee stated that since the precedence is already there that OTC products are included on the PDL, he recommended adding aspirin to the PDL.

MOTION: **John Lee motioned that the agents in this class, including aspirin, be considered therapeutic alternatives.**
SECOND: **Michael Karagiozis**
VOTES: **Unanimous**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health to add aspirin, Aggrenox®, Plavix®, dipyridamole and ticlopidine. He suggested that the Committee may want to consider not adding ticlopidine to the PDL due to the toxicity issues.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Lee stated that as a cardiologist, a number of his patients need an aspirin and Plavix®. Many of these patients have had a stroke and are seeing a neurologist. The representative of Aggrenox®, John Robinson, Boehringer Ingelheim, said that adding dipyridamole to aspirin doesn't increase the risk of bleeding compared to aspirin alone. He asked Mr. Robinson if it would be correct to assume or conclude that aspirin and Plavix® has its risk of hemorrhage but adding Aggrenox® to those two does not.

Mr. Robinson replied that there is no current data that specifically looks at the combination of aspirin and Plavix® and Aggrenox®. There has been a study that showed that patients for prevention of second ischemic stroke who were taking the combination of Plavix® plus aspirin had increased incidence of adverse outcomes. Dr. Lee asked if Mr. Robinson is aware of any additional risk of adding dipyridamole on top of aspirin and Plavix®. He offered to contact his drug information unit to provide updated information for the Committee.

MOTION: **John Lee motioned to accept First Health's recommendation to add aspirin, Aggrenox®, Plavix®, dipyridamole to the PDL.**
SECOND: **Michael Karagiozis**
VOTES: **Unanimous**
MOTION CARRIED

IV. Established Drug Classes for Review

A. Triglyceride Lowering Agents

Public Comment

Arezo Fathie, MD, spoke in support of Lovaza®. She said that several case studies show the benefit of Lovaza® formerly known as Omacor®. It is an omega-3 fatty acid product that helps lower triglycerides, lowers LDL and has a tendency to increase the HDL. In patients with recurrent pancreatitis, there is a risk of liver damage and myositis with

statins, Tricor® or fenofibrates. She cited cases in which she prescribed Lovaza® and the patients showed improvement. She stated that in her experience, obtaining prior authorization (PA) from Medicaid has been a time consuming process for her and her staff. Compiling the information and completing the forms for Medicaid as well as private insurance can take one to four hours.

Darrell Faircloth asked if Dr. Fathie has any affiliation with drug manufacturers and she replied no.

David Chan asked why she felt that Lovaza® was better than any over-the-counter (OTC) product. She replied that the OTC products are hard to qualify. She doesn't know what the actual values of the EPA and DHA are in those and there seems to be more side effects because the OTC products do not undergo the same purification process as Lovaza®.

Ms. Flynn noted that Dr. Prabhu joined the meeting at 1:07 p.m. and Dr. Lee joined the meeting at 1:11 p.m.

E.J. Milas, Glaxo Smith Kline, spoke in support of Lovaza®. He stated that Lovaza® is a prescription omega-3 ethyl ester consisting of a minimal 920 mg of natural derived omega-3 fatty acids primarily EPA and DHA. In the treatment of patients with very high triglycerides, there was a reduction of 45% at 4 gm per day. Lovaza® received a labeling update in June 2007, for patients with triglycerides 200 to 499 in combination with a statin. That labeling was added by the FDA but the indication was not granted. There was an additional 30% reduction in triglycerides and no adverse events with elevated liver enzymes, rhabdomyolysis or myositis associated with combination therapy. Lovaza® has a remarkable safety profile, is well-tolerated and there are no clinically significant drug-drug interactions expected with Lovaza®.

Dr. Karagiosis asked if Lovaza® has an indication for pancreatitis and Mr. Milas replied that Lovaza® does not have an indication for pancreatitis per se but for patients at risk for pancreatitis.

Dr. Monaghan asked for clarification regarding the clinical indication. Mr. Milas stated that the clinical indication is for patients with very high triglycerides above 500. The labeling update was triglycerides 200 to 499 in combination with a statin which was approved by the FDA but the indication was not. The FDA has changed the parameters for what they want for an indication; they want to show mortality reduction in patients with triglycerides 200 – 499 in order to get the indication. Dr. Monaghan asked regarding outcomes data and Mr. Milas replied that there are no outcomes data in patients with very high triglycerides. Lovaza® does have outcomes in European-based studies both in heart failure where there was a 9% reduction in total mortality versus Crestor® which had no reduction in mortality in those patients. In another European study conducted in the mid to late '90s, Lovaza had a 20% reduction in cardiac events, cardiac death and 15% in total mortality.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this class was reviewed at the annual review in June 2008. At that time, gemfibrozil and Tricor® (fenofibrate) were maintained on the PDL; Lovaza® was not added. The NCPE Guidelines for high risk patients recommend either fibric acid derivatives or nicotinic acid either as monotherapy or in combination with statins in the presence of elevated triglycerides and/or low HDL-C. The fibric acid derivatives have been shown to reduce mortality and morbidity in both primary and secondary prevention trials. They lower triglyceride levels and raise HDL-C to a greater extent than do the statins. The other product included in this sub-category for review is the omega-3 fatty acids. Currently, there is only one legend product available, Lovaza® (omega-3-acid ethyl ester), previously known as Omacor®. Omega-3 fatty acids are available at lower concentrations over-the-counter. Lovaza® is currently indicated for triglyceride levels exceeding 500. There has recently been a labeling change but not an indication change.

Lovaza's® ability to reduce triglycerides is well documented. There are no strong peer review articles allowing the manufacturer to include it in the product literature nor consensus guidelines which include Lovaza® as a recommended or first-line agent. It is the recommendation of DHCFP and First Health that gemfibrozil, Tricor® and Lovaza® be considered therapeutic alternatives within this class.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Michael Karagiozis motioned that the agents in this class be considered therapeutic alternatives.
SECOND: John Lee
VOTES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to this class. He reinforced the fact that drugs not on the PDL are available through the PA process if exception criteria are met; e.g.; therapeutic failure of two preferred medications, unacceptable side effects, allergy to preferred medications within the same class.

Ms. Flynn noted that Dr. Kalinowski joined the meeting at 1:26 p.m.

Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Karagiozis advocated that the approval process for this drug be no more than writing on the prescription that the patient needs this drug as an alternative. In his practice and as stated in public testimony, there are a number of patients where traditional first-line therapy is not an option even with triglycerides of 250. It's his belief that is why the FDA included that in the package insert without giving the indication. There are a number of patients who do not have a triglyceride greater than 500 but for whom traditional triglyceride lowering agents are inappropriate or dangerous choices. For those patients, Lovaza® works well.

Dr. Monaghan stated that the State-approved PDL exception process is a fax request that is required to be turned around within 24 hours and/or the 24 hour/7 day per week Clinical Call Center. The concerns expressed are addressed in the PDL exception criteria. To write something on the prescription would take regulation changes and Ms. Griffith agreed stating that would require a policy change. ICD-9 codes are allowed for some diagnoses but it is not known what diagnosis code could be applied in this case.

Dr. Lee asked Dr. Karagiozis how frequent it is that his patients can't tolerate or don't respond to the fibrates. Dr. Karagiozis replied that it's less to do with levels over 500 but more to do with the other drugs the patient is on or their concomitant disease states.

David Chan stated that from a pharmacy practice standpoint, he does not see many prescriptions for Lovaza®. Dr. Monaghan added that this could be due to the fact that Lovaza® has not been accepted as first-line therapy and it's probably fairly high on tiers which this Committee does not consider.

Dr. Monaghan stated that if the Committee would like to include in the motion an ICD-9 diagnosis code on the prescription to bypass the PA process, First Health can research and identify the appropriate diagnosis and communicate it to the Committee for agreement.

MOTION: **Michael Karagiozis motioned that prescriptions for Lovaza® that include the appropriate ICD-9 diagnosis code (code to be**

determined which includes patients with hepatic dysfunction, pancreatitis, hypertriglyceridemia) will bypass the prior authorization process.

SECOND: **R.D. Prabhu**

Dr. Shea asked if there is any utilization data.

Dr. Monaghan responded that Medicaid data indicates Lovaza® has approximately a 10% market share. In general practice, it's not heavily used.

Dr. Karagiozis stated that in the patient population where it's necessary, it's the only alternative.

Several Committee members reiterated that the drug, if non-preferred, will continue to be available through the PA process.

AYES: **Prabhu, Karagiozis, Kalinowski, Flynn**

NAYES: **Luebke, Chan, Lee, Shea**

Mr. Faircloth stated that there are four affirmative votes; the motion fails.

B. Stimulants and Related Agents

Public Comment

Lee Boyle, Shire Pharmaceuticals, provided the Committee with an update on what has occurred since Vyvanse® was added to the PDL last year. Additional strengths of 20mg, 40mg, and 60mg doses have been approved. An adult indication has also been approved.

Laura Litzenberger, Ortho McNeil Janssen, spoke in support of retaining Concerta® on the PDL. Concerta® is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children ages six years and older, adolescents and adults up to age 65. Concerta's® delivery system is unique in that it provides an ascending profile of the release of methylphenidate resulting in a more constant delivery of the drug. It provides a duration of effect throughout the full twelve hours of the effect of the dosage form. Concerta® has 22% of the drug released immediately and 78% of the drug extended over the twelve hour period. Onset of effect is within an hour and the duration extends to the latter part of the day. The tablet is compromised resistant; it's almost impossible to break the tablet. When broken and put in water, the tablet turns to gel and it's very difficult to extract the methylphenidate. The gel cannot be injected or used intranasally. Due to the ascending profile, there is a lower early exposure of the dopamine receptors in the brain so there is no reinforcing effect when this drug is given and less drug likeability with this product due to the release mechanism. Concerta® has proven to be effective in the treatment of ADHD in adults and adolescents and children.

Drug Class Review Presentation – First Health Services

Dave Wuest stated that this drug class was last reviewed in June 2008. At that time, no changes were made to the PDL for this class. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Chad Luebke motioned that the agents in this class be considered therapeutic alternatives.

SECOND: David Chan

VOTES: Unanimous

MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Dave Wuest stated that it is the recommendation of DHCFP and First Health that Concerta® be retained on the PDL and Metadate® CD be removed from the PDL.

MOTION: Constance Kalinowski motioned that Concerta® be retained on the PDL and Metadate® CD be removed from the PDL.
SECOND: Michael Karagiozis
VOTES: Unanimous
MOTION CARRIED

Dave Wuest stated that since the annual review in June 2008, the FDA has mandated that Strattera® add a black box warning to the package insert regarding suicidal ideations. It is the recommendation of DHCFP and First Health to remove Strattera® from the PDL. Patients currently on Strattera® can be grandfathered in for continued therapy.

Dr. Kalinowski felt Strattera® should be retained on the PDL because there is a different niche for Strattera®. There are clinical circumstances where a clinician may prefer to avoid a stimulant and go with Strattera®. Many of her patients often have hyperactivity and psychiatric side effects from stimulants and for many of these individuals, it's preferable to go directly to Strattera® despite the black box warning.

MOTION: Constance Kalinowski motioned that Strattera® remain on the PDL.
SECOND: John Lee
VOTES: Unanimous
MOTION CARRIED

V. Report by FHSC on Brand Name Preferred Drugs Converted to Generic Status and Line Extensions

Jeff Monaghan referred to the report in the meeting packet and noted the addition of two drugs that are not included in the "PDL Brand Name Drugs Converted to Generic" report which will also be changed to reflect the conversion of brand-name to generic. These are Imitrex® tablets to sumatriptan and Focalin® immediate release to dexmethylphenidate.

A new drug recently released which falls into an existing PDL category, brand name Sancuso® (granisetron transdermal) will be reviewed at the annual review scheduled for June 2009.

VI. Review of Next Meeting Location, Date, and Time

The next meeting is scheduled for March 26, 2009, in Las Vegas.

VII. Public Comment

Sandy Sierwski, Pfizer, asked if the addition of Aricept® tablets to the PDL includes Aricept® ODT tablets and Dr. Monaghan replied that it does not.

VIII. Adjournment

MOTION: Michael Karagiozis motioned to adjourn the meeting.
SECOND: Chris Shea
VOTES: Unanimous
MOTION CARRIED

Meeting adjourned at 2:53 p.m.